

### **Remarks**

Claims 21-26 are pending in the application. Reconsideration of the application in view of the remarks presented below is respectfully requested.

### **35 U.S.C. 103(a) Rejections**

*Claims 21-23 and 25-26 stand rejected under 35 U.S.C 103(a) as being unpatentable over Bamdad (US 6,306,584) in view of Backhaus et al. (US 5,869,001).*

Applicant respectfully traverses the rejection. The rejection under 35 USC 103(a) is based on the position of the Examiner that Bamdad teaches a homogeneous surface modification layer. Applicant does not agree. The surface modification layer of Bamdad is not homogeneous because it is made up of two different self-assembling molecules (SAM) that are mixed together. Specifically, Bamdad teaches a layer made up of first and second SAM that are mixed together to form a monolayer. Bamdad reports at col.3, lines 47-63 that:

According to this aspect a self-assembled mixed monolayer, formed of a first species and a second species, is adhered to the surface. The first species has a formula  $X-R-Ch-M-BP$ , where X, R, Ch, M, and BP are each selected such that X represents a functional group that adheres to the surface, R represents a spacer moiety that promotes self-assembly of the mixed monolayer, Ch represents a chelating agent that coordinates a metal ion, M represents a metal ion, and BP represents a binding partner of the biological molecule. The binding partner is coordinated to the metal ion.

The second species is selected to form a mixed, self-assembled monolayer with the first species, and according to a preferred aspect the second species has a formula,  $X-R-O-(CH_2CH_2-O)_n-H$ , in which X represents a functional group that adheres to the surface, R represents a spacer moiety that promotes formation of a self-assembled monolayer of a plurality of the molecules, and n is from one to ten.

Because Bamdad teaches SAM layers that are mixtures of first and second SAMs, Bamdad fails to teach or suggest a homogeneous surface modification layer. That is, Bamdad's mixed SAM layer is not homogeneous because it is not made up of a single type of SAM.

Backhaus et al. does not cure the deficiency in Bamdad. Backhaus et al. simply states that a hydrophillic surface coating can be used to assist with the spreading of sample liquid on a substrate. According to Backhaus et al., alkyl chains with terminal thiol groups are suitable for coating gold surfaces because the thiol group binds well to gold surfaces. Backhaus et al. also

states that alkyl chains with sulfonic acid groups, phosphate residue, or carboxyl groups provide a hydrophilic coating (col. 7, lines 45-49). Backhaus et al. does not provide one of skill in the art with motivation to modify Bamdad contrary to Bamdad's express teachings in order to have a homogeneous surface modification layer.

In view of the foregoing, the rejection of claims 21-23 and 25-26 under 35 U.S.C. 103(a) as being unpatentable over Bamdad (US 6,306,584) in view of Backhaus et al. (US 5,869,001) has been overcome and should be withdrawn.

Claim 24 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad in view of Backhaus et al. as applied to claim 21 above, and further in view of Blackman (U.S. Patent No. 4,813,538).

Applicant respectfully traverses the rejection. Claim 24 depends from independent claim 21, and therefore includes all of the features of claim 21. Claim 21 is patentable for the reasons discussed hereinabove. Therefore, claim 24 is patentable for at least the same reasons. Accordingly, withdrawal of the rejection of claim 24 under 35 USC 103(a) as being unpatentable over Bamdad in view of Backhaus et al. and further in view of Blackman (US 4,813,538) has been overcome and should be withdrawn.

### **Double Patenting Rejections**

Claim 26 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,577 in view of Bamdad or Backhaus et al.

Upon notice that claim 26 is allowable over the art, applicant will timely file a terminal disclaimer over U.S. Patent No. 6,716,577 in order to overcome the nonstatutory obviousness-type double patenting rejection.

Claims 21 and 26 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of U.S. Patent No. 6,558,528(Matzinger) in view of Backhaus et al.

Applicant respectfully traverses the rejection. Claims 21-23 of Matzinger are drawn to kits and systems for determining the concentration of an analyte in a physiological sample. The kit of claim 21 comprises: (a) an electrochemical test strip card comprising at least two electrochemical test strip precursors configured to be singulated from said test strip card, wherein each of said precursors comprises: (i) a reaction chamber bounded by opposing electrodes and comprising a reagent composition; and (ii) an integrated desiccant; wherein prior to after singulation of said card each reaction chamber is in gaseous communication with said integrated desiccant; and (b) at least one of: (i) a means for obtaining said physiological sample; and (ii) an analyte standard. The kit of claim 22 further includes a meter.

The system of claim 23 comprises: (a) an electrochemical test strip comprising: (i) a reaction chamber bounded by opposing electrodes and comprising a reagent composition; and (ii) a desiccant integrated into said electrochemical test strip wherein during use of said electrochemical test strip said reaction chamber is in gaseous communication with said desiccant; and (b) a meter.

Claims 21-23 do not teach or suggest a kit or system for use in determining the concentration of an analyte in a physiological sample, wherein the kit or system comprises an electrochemical test strip comprising a reaction zone defined by opposing working and reference metallic electrodes separated by a spacer layer, wherein at least one of said first and second metallic electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules having a first sulfhydryl end group and a second sulfonate end group, wherein said sulfhydryl and sulfonate end groups are separated by a lower alkyl linker group.

Backhaus et al. does not cure the deficiency in claims 21-23 of Matzinger. Backhaus et al. simply states that a hydrophilic surface coating can be used to assist with the spreading of sample liquid on a substrate. According to Backhaus et al., alkyl chains with terminal thiol groups are suitable for coating gold surfaces because the thiol group binds well to gold surfaces. Backhaus et al. also states that alkyl chains with sulfonic acid groups, phosphate residue, or carboxyl groups provide a hydrophilic coating (col. 7, lines 45-49). Backhaus et al. does not provide one of skill in the art with motivation to modify Matzinger to provide a homogeneous surface modification layer of self assembling molecules having a first sulfhydryl end group and a

second sulfonate end group, wherein said sulfhydryl and sulfonate end groups are separated by a lower alkyl linker group. In addition, there would be no motivation to combine the teachings of Matzinger with Backhaus et al. For example, Backhaus et al. does not comprise an electrochemical test strip, nor a redox reagent system, but rather is based on detection of radiation emitted from the sample.

In view of the foregoing, withdrawal of the rejection of claims 21 and 26 has been overcome and should be withdrawn.

*Claims 21-26 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-24 of U.S. Patent No. 6,855,243(Kahn) in view of Backhaus et al.*

Applicant respectfully traverses the rejection. Claims 19-24 of Kahn are drawn to kits and systems for determining the concentration of an analyte in a physiological sample. The kit of claim 19 comprises (a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition present in each of said reaction zones, wherein each of said reaction zones are provided by a bore through said spacer layer and further wherein each of said reaction zones has its own fluid ingress channel to provide for fluid communication between said reaction zones and the external environment of said test strip; and (b) at least one of; (i) a means for obtaining said physiological sample; and (ii) an analyte standard. The kit of claim 20 further includes a lance, and the kit of claim 21 further includes a meter.

The system of claim 22 comprises (a) an electrochemical test strip comprising a plurality of reaction zones defined by opposing working and reference electrodes separated by a spacer layer and a reagent composition present in each of said reaction zones, wherein each of said reaction zones are provided by a bore through said spacer layer and further wherein each of said reaction zones has its own fluid ingress channel to provide for fluid communication between said reaction zones and the external environment of said test strip; and (b) a meter. The system of claim 23 further comprises a means for obtaining said physiological sample, and the system of claim 24 further comprises an analyte standard.

Claims 19-24 of Kahn do not teach or suggest a kit or system for use in determining the concentration of an analyte in a physiological sample, wherein the kit or system comprises an electrochemical test strip comprising a reaction zone defined by opposing working and reference metallic electrodes separated by a spacer layer, wherein at least one of said first and second metallic electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules having a first sulfhydryl end group and a second sulfonate end group, wherein said sulfhydryl and sulfonate end groups are separated by a lower alkyl linker group.

Backhaus et al. does not cure the deficiency in claims 19-24 of Kahn. Backhaus et al. simply states that a hydrophillic surface coating can be used to assist with the spreading of sample liquid on a substrate. According to Backhaus et al., alkyl chains with terminal thiol groups are suitable for coating gold surfaces because the thiol group binds well to gold surfaces. Backhaus et al. also states that alkyl chains with sulfonic acid groups, phosphate residue, or carboxyl groups provide a hydrophillic coating (col. 7, lines 45-49). Backhaus et al. does not provide one of skill in the art with motivation to modify Kahn to provide a homogeneous surface modification layer made up of self assembling molecules having a first sulfhydryl end group and a second sulfonate end group, wherein said sulfhydryl and sulfonate end groups are separated by a lower alkyl linker group. In addition, there would be no motivation to combine the teachings of Kahn with Backhaus et al. For example, Backhaus et al. does not comprise an electrochemical test strip, nor a redox reagent system, but rather is based on detection of radiation emitted from the sample.

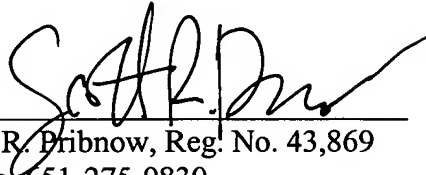
In view of the foregoing, withdrawal of the rejection of claims 21-26 has been overcome and should be withdrawn.

**Conclusion**

Applicant submits that pending claims 21-26 are in condition for allowance.  
Allowance of claims 21-16 at an early date is respectfully requested.

Respectfully submitted,

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